K130049

NIPRO MEDICAL CORPORATION
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FEB 14 2013

510(k) Summary: Monoject 12mL Syringe

807.92(a)(1)

Applicant: Nipro Medical Corporation
3150 NW 107th Ave.
Miami FL 33172
Tel: 305-599-7174

Establishment Reg.: 1056186

Contact Person: Jessica Oswald-McLeod
Regulatory Affairs Specialist

Date of summary preparation: January 9, 2013

807.92(a)(2)

Trade Name: Monoject 12mL Syringe
Common Name: syringe, piston
Classification Name: piston syringe
Regulation Number: 21 CFR 880.5860
Panel: 80
Product Code: FMF

807.92(a)(3)

Legally marketed substantial equivalent device:
K944355 – NIPRO Disposable Syringe

807.92(a)(4)

Description of device:
The Monoject 12 mL Syringe is a standard piston syringe without needle. It consists of 3 parts; a calibrated hollow barrel, with a moveable plunger and attached gasket. The barrel is made from polypropylene and is designed with clear graduation for easy use. The barrel nozzle has an ISO 594 compliant male 6% taper luer lock tip for fitting any female luer taper hub that is also ISO 594 compliant. The plunger is made from polypropylene. The gasket is made from thermoplastic elastomer material. The syringe is individually packaged in a peel blister that ensures the sterility of the device until the package is opened. This is a single use only device. An inner box contains 100 devices, and the outer box contains 10 inner boxes. This syringe is sterilized by gamma irradiation.

807.92(a)(5)

Indications for Use:
The syringe is intended to inject or withdraw fluids from the body.

807.92(a)(6)

Comparison of technological characteristics:

The syringe is substantially equivalent to the predicate device in the following technological characteristics:

- Physical characteristics
- Operational mode
- Basic Scientific Technology
- Intended Use

807.92(b)(1)

Non-clinical tests submitted:

Performance testing was conducted to verify that the device is safe and effective for its intended use. These tests include: liquid leakage, air leakage, separation force, unscrewing torque, ease of assembly, resistance to overriding, stress cracking, tolerance on graduation capacity, maximum dead space, air leakage past syringe piston during aspiration and for separation of piston and plunger, air and liquid leakage at piston under compression, minimum over length of scale to nominal capacity mark, force required to operate plunger, individual package integrity, chemical testing, bacterial endotoxin testing and biocompatibility testing. These tests along with their associated results and conclusions are included in this submission.

807.92(b)(2)

Clinical tests:

This submission does not warrant any clinical testing, therefore no clinical testing performed for or provided in this submission.

807.92(b)(3)

Conclusions drawn from non-clinical and clinical tests:

The results of the performance testing and the comparison of technological characteristics with the predicate device demonstrate that the Monoject 12mL Syringe performs equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

Nipro Medical Corporation
Ms. Jessica Oswald-Mcleod
Regulatory Affairs Specialist
North American Division
3150 N.W. 107th Avenue
MIAMI, FL 33172

Re: K130049
Trade/Device Name: Monoject 12ml Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: January 4, 2013
Received: January 17, 2013

Dear Ms. Oswald-Mcleod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130049

Device Name: Monoject 12mL Syringe

Indications for Use:

The syringe is intended to inject or withdraw fluids from the body.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director, DAGRID
2013.02.15 13:17:23 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

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